

CIRCUIT COURT  
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CITY OF ROANOKE

VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

DANA MARLENE BRADLEY,

*Plaintiff,*

v.

INSIGHT HEALTH CORP.,

CT Corporation System, Its Registered Agent

4701 Cox Road, Suite 301

Glen Allen, Virginia 23060

(Henrico County)

JOHN M. MATHIS, M.D.,

2923 Franklin Rd., S.W.

Roanoke, Virginia 24014

(Roanoke City)

AND

IMAGE GUIDED PAIN MANAGEMENT,

P.C.,

Heman A. Marshall, Esq., Its Registered Agent

Woods Rogers, PLC

Wells Fargo Tower, 14<sup>th</sup> Floor

Roanoke, Virginia 24011

(Roanoke City)

*Defendants.*

Case No: CL12-2576

COMPLAINT

COMES NOW Dana Marlene Bradley ("Mrs. Bradley"), by counsel, and files this Complaint against the Defendants and states as follows:

PARTIES

1. Mrs. Bradley is a citizen of the Commonwealth of Virginia.

2. Insight Imaging-Roanoke is located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

3. Insight Imaging-Roanoke is a registered fictitious name of Image Guided Pain Management, P.C. ("Image Guided").

4. Insight Health Corp. ("Insight Health") transacts business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.

5. Insight Health has not registered the fictitious name of Insight Imaging-Roanoke in violation of Virginia Code §§ 59.1-69 and 59.1-70.

6. At all times and places pertinent to this action, Insight Health transacted business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.

7. At all times and places pertinent to this action, Insight Health owned, operated and controlled Insight Imaging-Roanoke.

8. Unless otherwise specified in this Complaint, references to Insight Imaging-Roanoke include Image Guided and Insight Health.

9. At all times and places pertinent to this action, Insight Health made the actual decisions and arrangements relating to the selection, procurement, and preparation of drugs administered at Insight Imaging-Roanoke, including the epidural steroid drug which is at issue in this case.

10. Insight Health is incorporated in the State of Delaware.

11. Insight Health's principal place of business is in the State of California.

12. At all times and places pertinent to this action, Insight Health advertised to the public that it was a national provider of diagnostic imaging services.

13. At all times and places pertinent to this action, Insight Health advertised to the public that it was committed to providing the best imaging experience possible, and it called this "Patients First care".

14. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was to "do the right thing".

15. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was integrity.

16. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was ethics.

17. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over profits.

18. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over expediency.

19. At all times and places pertinent to this action, Insight Health advertised to the public that it offered the highest quality of care through a network of outpatient imaging centers and mobile facilities.

20. At all times and places pertinent to this action, Insight Health advertised to the public that one of its centers was Insight Imaging-Roanoke, located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

21. At all times and places pertinent to this action, Insight Health advertised to the public that one of the modalities that it provided at Insight Imaging-Roanoke was pain management image-guided therapeutics.

22. Insight Health procured, received, and provided to Mrs. Bradley the epidural steroid injection which is at issue in this case.

23. Dr. John M. Mathis ("Dr. Mathis") is a citizen of the Commonwealth of Virginia.

24. At all times and places pertinent to this action, Insight Imaging-Roanoke allegedly designated Dr. Mathis as its medical director.

25. At all times and places pertinent to this action, Insight Imaging-Roanoke allegedly held Dr. Mathis out to the public as its medical director.

26. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke designated him as its medical director without his permission or consent.

27. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke held him out to the public as its medical director without his permission or consent.

28. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke never asked him to be its medical director.

29. On information and belief, Dr. Mathis would allege that he never gave his permission or consent to be Insight Imaging-Roanoke's medical director.

30. On information and belief, Dr. Mathis would allege that he was never compensated to be Insight Imaging-Roanoke's medical director.

31. On information and belief, Dr. Mathis would allege that he never acted as Insight Imaging-Roanoke's medical director.

32. If Dr. Mathis agreed to be or acted as the medical director of Insight Imaging-Roanoke during the times and places pertinent to this action, then he was ultimately responsible for Insight Imaging-Roanoke's choices regarding the procurement of drugs, such as Mrs. Bradley's epidural steroid drug which is at issue in this case.

33. If Dr. Mathis did not agree to be or act as the medical director of Insight Imaging-Roanoke during the times and places pertinent to this action, then Insight Imaging-Roanoke falsely designated and held out Dr. Mathis to the public as its medical director, and Insight Health delegated to non-medical staff the important patient care function of choosing safe and effective drugs for its patients.

34. At all times and places pertinent to this action, Dr. Mathis was an employee and/or agent of Insight Imaging-Roanoke acting in the course and scope of his employment or agency.

35. At all times and places pertinent to this action, Insight Imaging-Roanoke acted through its employees and agents including, but not limited to, Dr. Mathis.

36. At all times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for Dr. Mathis' actions and omissions.

37. At all times and places pertinent to this action, Insight Imaging-Roanoke also did business through other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel.

38. At the times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for the actions and omissions of its other employees and agents located in

Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel.

39. Image Guided is incorporated in the Commonwealth of Virginia.
40. Image Guided's principal place of business is in the City of Roanoke, Virginia.

JURISDICTION AND VENUE

41. Subject matter jurisdiction is proper pursuant to Virginia Code § 17.1-513.
42. Personal jurisdiction over Insight Health is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3), (4) & (6).
43. Personal jurisdiction over Image Guided and Dr. Mathis is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3) & (6).
44. Venue is proper pursuant to Virginia Code §§ 8.01-262(1) & (2).

FACTS

45. At all times and places pertinent to this action, Insight Imaging-Roanoke and its employees and agents had a healthcare provider-patient relationship with Mrs. Bradley.

46. Insight Imaging-Roanoke and its employees and agents owed Mrs. Bradley numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers; to provide the best imaging experience possible; to act ethically; to act with integrity; to do the right thing; to place patient care first; to place ethics, integrity, doing the right thing, and patient care above profits; and to ensure that the drugs that they gave to patients were safe and effective.

47. At all times and places pertinent to this action, Mrs. Bradley relied upon the advice and treatment provided by Insight Imaging-Roanoke and its employees and agents, which

had specialized training and superior knowledge regarding treatment, use of drugs, and the source of drugs.

48. Insight Imaging-Roanoke and its employees and agents intended to and in fact did use methylprednisolone acetate in epidural steroid injections, including the injection provided to Mrs. Bradley which is at issue in this case.

49. The use of methylprednisolone acetate in epidural steroid injections by Insight Imaging-Roanoke and its employees and agents has never been approved by the Food and Drug Administration (“FDA”).

50. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

51. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that use of methylprednisolone acetate in epidural steroid injections is an off-label use.

52. Insight Imaging-Roanoke and its employees and agents knew, or should have known, the importance of purchasing safe and effective drugs for their patients and this importance was greatly heightened by the fact that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

53. Insight Imaging-Roanoke and its employees and agents knew, or should have known, the danger to which their patients would be exposed if they purchased unsafe and/or ineffective drugs for its patients.

54. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the best way of ensuring safe and effective drugs for their patients was to purchase

such drugs from an FDA-regulated manufacturer or an accredited pharmacy that complied with all federal and state laws.

55. Insight Imaging-Roanoke and its employees and agents assumed the responsibility for purchasing safe and effective drugs for its patients, including Mrs. Bradley.

56. Insight Imaging-Roanoke and its employees and agents assumed the responsibility for verifying that the pharmacy from which they purchased drugs was safe, reliable, accredited and in compliance with all federal and state laws.

57. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (“NECC”) was a compounding pharmacy located in Framingham, Massachusetts.

58. Compounding pharmacies are generally small operations that engage in mixing (or “compounding”) drug products for specific patients, pursuant to a valid prescription.

59. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.

60. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists.

61. Although NECC operated in Massachusetts, it was also required to comply with Virginia law in order to fill prescriptions in Virginia.

62. NECC was required to be licensed and registered with the Virginia Board of Pharmacy.

63. Methylprednisolone acetate is a knock-off of the brand name drug, Depo-Medrol, which is manufactured by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. (“Pfizer”).

64. Other FDA-regulated drug manufacturers produce sterile generic versions of methylprednisolone acetate (with and without preservatives) in facilities that are also regulated, controlled, and inspected by the FDA.

65. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that sterile methylprednisolone acetate (with and without preservatives) may be purchased in generic from FDA-regulated drug manufacturers in the United States.

66. Rather than producing small quantities of this knock-off Depo-Medrol, NECC engaged in the very risky process of producing and marketing vast batches of this drug, thousands at a time.

67. NECC did so through a process of taking non-sterile ingredients and placing them into an aqueous mixture that then had to be rendered sterile.

68. Even without the large batches, NECC's process made the methylprednisolone acetate a high risk compound.

69. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC engaged in the process of producing and marketing vast batches of this drug.

70. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's process made the methylprednisolone acetate a high risk compound.

71. NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate.

72. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate.

73. Under Virginia law, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code §54.1-3410.2(E).

74. NECC failed to comply with USP-NF standards.

75. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not compliant with USP-NF standards.

76. Moreover, pharmacists and pharmacies may not engage in “the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products.” Virginia Code §54.1-3410.2(H)(2).

77. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was producing enormous batches of commercially available methylprednisolone acetate, which NECC then sold in bulk.

78. Within just two months during the general time frame pertinent to this action, Insight Imaging-Roanoke alone purchased and injected over 600 doses of methylprednisolone acetate from NECC.

79. Such large-scale production of methylprednisolone acetate, a commercially available drug, is illegal under Virginia Code § 54.1-3410.2(H)(2).

80. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC’s large-scale production of methylprednisolone acetate and subsequent sale without individual prescriptions violated Virginia law.

81. NECC is not accredited by the Pharmacy Compounding Accreditation Board (“PCAB”) or any other similar organizations, such as The Joint Commission, that offer

independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

82. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not an accredited compounding pharmacy.

83. There are accredited compounding pharmacies in the Commonwealth of Virginia and the United States, but Insight Imaging-Roanoke and its employees and agents chose not to purchase drugs from them, electing instead to buy methylprednisolone acetate from an unaccredited, wholesale distributor pharmacy facility in Massachusetts—a state known to have less stringent enforcement standards for compounding pharmacies than the Commonwealth of Virginia.

84. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that there are accredited compounding pharmacies in the Commonwealth of Virginia and the United States.

85. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that Massachusetts, the state in which NECC was located, had less stringent enforcement standards for compounding pharmacies than the Commonwealth of Virginia.

86. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the methylprednisolone acetate that it sought to purchase was to be used in epidural steroid injections allowing direct contact with patients' central nervous systems, including Mrs. Bradley's central nervous system

87. NECC produced methylprednisolone acetate without preservatives.

88. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC produced methylprednisolone acetate without preservatives.

89. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that preservative free methylprednisolone acetate heightens the danger of the drug if it is not produced to the highest standards including a highly sterile environment.

90. Sterilization techniques, quality control measures, highly sterile environments and sterility testing are crucial to properly producing methylprednisolone acetate without preservatives.

91. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that sterilization techniques, quality control measures, highly sterile environments, and sterility testing were crucial to the methylprednisolone acetate that they were going to inject in its patients' spinal canals.

92. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was an unaccredited compounding pharmacy producing a high-risk compound, starting with non-sterile components.

93. NECC's drug production operations took place in an aged building surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro.

94. NECC's drug production facility received many varieties of garbage and waste that were sorted, stored, and manipulated just outside the back door of the NECC facility.

95. These waste products include used mattresses, recycled on-site from sources such as hospitals, prisons, hotels, and dormitories.

96. A photograph of NECC's facility is attached as **Exhibit A**.

97. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts while NECC lists its address as 697 Waverly Street.

98. The marketing company for NECC, however, lists its address as the same as the waste facility.

99. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's drugs and production processes were unsanitary, unsterile, and lacked adequate quality control measures, and that NECC operated in a facility surrounded by a garbage and waste center.

100. Other image guided pain management clinics in the Roanoke area recognized NECC as a dangerous source of methylprednisolone acetate.

101. These other clinics chose to pay more to obtain methylprednisolone acetate from reliable sources, specifically rejecting the lower prices offered by NECC.

102. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was a dangerous source of methylprednisolone acetate.

103. On information and belief, NECC charged Insight Imaging-Roanoke less for methylprednisolone acetate than did Pfizer, other FDA approved manufacturers of the generic, and other accredited or reliable compounding pharmacies.

104. At all times and places pertinent to this action, Insight Imaging-Roanoke was one of only two pain management clinics in the Commonwealth of Virginia that chose to purchase methylprednisolone acetate from NECC.

105. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with and be licensed by the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

106. NECC was registered in the Commonwealth of Virginia as a non-resident pharmacy, but it is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

107. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in the Commonwealth of Virginia.

108. Insight Imaging-Roanoke and its employees and agents knew that the methylprednisolone acetate that they would purchase from a pharmacy would be injected directly into patients' spinal canals so as to enter the central nervous system.

109. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.

110. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the methylprednisolone acetate that they would purchase from a pharmacy acts as an immune system suppressing agent, thus weakening the patient's natural ability to fight off pathogens that could possibly be included in the injection.

111. Despite what Insight Imaging-Roanoke and its employees and agents knew, or should have known, concerning NECC, they chose to purchase methylprednisolone acetate from NECC, which was an unaccredited, sprawling compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches (making mistakes more likely); (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility

before releasing them for distribution; (g) did not comply with USP-NF standards; and (h) violated several provisions of Virginia statutes designed to protect Virginia citizens from substandard and adulterated prescription drugs.

112. Despite what Insight Imaging-Roanoke and its employees and agents knew, or should have known, concerning NECC, they voluntarily purchased methylprednisolone acetate from NECC in order to inject it into their patients' spinal canals, including Mrs. Bradley's spinal canal.

113. In addition, notwithstanding such knowledge, they voluntarily purchased methylprednisolone acetate wholesale from NECC without prescriptions.

114. On information and belief, Dr. Mathis would allege that this purchasing decision was made without his advice, consent, or knowledge.

115. On information and belief, Dr. Mathis would allege that at the times and places pertinent to this action he never knew that Insight Imaging-Roanoke and its employees and agents were purchasing the methylprednisolone acetate from NECC.

116. On information and belief, Dr. Mathis would allege that at the times and places pertinent to this action he never knew that the epidural steroid drug that he was injecting into patients' spinal canals, including Mrs. Bradley's spinal canal, came from NECC.

117. On information and belief, Dr. Mathis would allege that he never would have used the methylprednisolone acetate from NECC, including with Mrs. Bradley, if he had been informed that NECC was not an accredited compounding pharmacy.

118. On information and belief, Dr. Mathis would allege that he never would have used the methylprednisolone acetate from NECC, including with Mrs. Bradley, if he had been informed that NECC did not comply with all federal and state laws.

119. On information and belief, Dr. Mathis would allege that he never would have used the methylprednisolone acetate from NECC, including with Mrs. Bradley, if he had been informed that it was being produced in a facility located beside a garbage and waste facility.

120. On information and belief, Dr. Mathis would allege that he never would have used the methylprednisolone acetate from NECC, including with Mrs. Bradley, if he had been informed that it was being produced in a facility that did not comply with USP-NF standards.

121. On information and belief, Dr. Mathis would allege that the actions of Insight Imaging-Roanoke and its employees and agents deprived him from making informed and reasonable patient care decisions on behalf of his patients, including Mrs. Bradley, concerning the information, and lack thereof, that they were provided concerning the epidural steroid drug.

122. In addition to Insight Imaging-Roanoke and its employees and agents apparently withholding information from Dr. Mathis, Insight Imaging-Roanoke and its employees and agents did not inform their patients, including Mrs. Bradley, that they were receiving a knock-off drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems as described in the preceding paragraphs.

123. On the contrary, Insight Imaging-Roanoke and its employees and agents provided their patients, including Mrs. Bradley, with invoices that falsely itemized the drug as "Depo-Medrol", the trademarked name brand drug manufactured by Pfizer.

124. The same invoices from Insight Imaging-Roanoke also falsely reference the National Drug Code, 0703-0051-01, (or an abbreviation of such code).

125. A redacted true and correct copy of this invoice is attached as **Exhibit B**.

126. Insight Imaging-Roanoke and its employees and agents also provided Mrs. Bradley and other patients with literature indicating that the injection that they had received was Depo-Medrol, the trademarked name brand drug produced by Pfizer.

127. A representative copy of this literature is attached as **Exhibit C**.

128. Further, Insight Imaging-Roanoke and its employees and agents falsely coded methylprednisolone acetate on Mrs. Bradley's medical and billing records using billing code J1040, the HCPCS code for the name brand drug produced by FDA-regulated Pfizer, as well as other FDA-regulated generic drug producers, such as Teva Parenteral Medicines, Inc., a/k/a SICOR Pharmaceuticals.

129. A compounded drug should not be billed with the J codes meant for commercially prepared, preservative free drugs.

130. Rather, the "unlisted" code, J3490, should be provided along with the name of the drug and the dosage administered.

131. Insight Imaging-Roanoke and its employees and agents falsely coded methylprednisolone acetate on Mrs. Bradley's medical and billing records using the National Drug Code, 0703-0051-01, a unique product code that contains an FDA-assigned labeler code unique to the manufacturer of the drug.

132. Rather than disclosing that the methylprednisolone acetate injected into Mrs. Bradley was a compounded drug from NECC, Insight Imaging-Roanoke and its employees and agents falsely used the unique NDC code assigned to the FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc., for single dose, 80 mg/mL, preservative free, methylprednisolone acetate.

133. A copy of a representative label for the Teva Parenteral drug is attached for reference as **Exhibit D**.

134. However, Teva Parenteral Medicines, Inc., a leading generic drug manufacturer, had nothing to do with the epidural steroid injection that was provided to Mrs. Bradley.

135. Any reference in the records from Insight Imaging-Roanoke and its employees and agents to this Teva national drug code is simply false and completely misleading.

136. Similarly, Mathis' medical documentation states that the drug injected into Mrs. Bradley's spinal canal was "Depo-Medrol", the name brand drug produced by Pfizer.

137. On information and belief, Dr. Mathis would allege that he referenced "Depo-Medrol" to indicate the name brand drug produced by Pfizer or a drug produced to the same high quality standards.

138. Mrs. Bradley never received Depo-Medrol or a drug produced to the same high quality standards from Insight Imaging-Roanoke and its employees and agents.

139. A true and correct copy of Dr. Mathis' report is attached as **Exhibit E**.

140. This report was provided to Mrs. Bradley's primary care physician who was serving as Mrs. Bradley's agent.

141. Insight Imaging-Roanoke and its employees and agents uniformly misrepresented that the knock-off drug obtained from NECC and injected into Mrs. Bradley's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory and/or they misrepresented that it was the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc. Both representations were false.

142. A redacted true and correct copy of a representative page from Mrs. Bradley's medical/billing records from Insight Imaging-Roanoke is attached as **Exhibit F**.

143. At all times and places pertinent to this action, the methylprednisolone acetate that Insight Imaging-Roanoke and its employees and agents voluntarily purchased from NECC and then sold and provided to their patients, including Mrs. Bradley, was contaminated with fungus, mold, and/or other contaminants.

Mrs. Bradley's Medical Timeline

144. In the summer of 2012, Mrs. Bradley had for some time been experiencing lower back and lower extremity pain. She was referred by her physician, Dr. Trevor Chapman, M.D., to Insight Imaging-Roanoke, where she was evaluated for nerve root compression.

145. After an examination conducted on August 2, 2012, Mrs. Bradley was scheduled for an epidural steroid injection with Insight Imaging-Roanoke.

146. The typical method for receiving such an injection requires radiological facilities that allow the proper placement of the shot in exactly the right place with the assistance of equipment such as a fluoroscope. An anesthesiologist or an interventional radiologist usually performs such a procedure.

147. Mrs. Bradley received the injection from Insight Imaging-Roanoke on or about August 29, 2012. The shot was administered by Dr. Mathis.

148. Upon receiving the injection, Mrs. Bradley never experienced any real improvement in her symptoms. To the contrary, within days of the injection, Mrs. Bradley began suffering severe lower back and lower extremity pain.

149. Mrs. Bradley was eventually diagnosed with fungal meningitis, a life-threatening disease, and was admitted to Carilion Roanoke Memorial Hospital on October 7, 2012. She was transferred to the ICU on October 15, 2012 and remained there for 11 days. She was then moved

to the Progressive Unit until she was discharged from the hospital on November 4, 2012. At that point, she was admitted to Raleigh Court Health Care Center.

150. Mrs. Bradley has endured intensive treatment, suffered a stroke and multiple blood clots, spent two weeks in the Intensive Care Unit (ICU) and significant time rehabilitating in a nursing home, all due to the defendants' tainted drug being injected into her central nervous system.

151. Mrs. Bradley's fungal meningitis was a direct and proximate result of receiving a tainted injection of methylprednisolone acetate from the defendants.

152. This lawsuit seeks fair compensation to the fullest extent permitted under the law of the Commonwealth of Virginia for Mrs. Bradley's unnecessary infection and personal injury.

**COUNT I – NEGLIGENCE *PER SE***

153. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

154. Virginia Code § 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

155. Virginia law also establishes that:

... the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Haltermann v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982).

Schlimer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

156. Virginia Code §§ 54.1-3400 *et seq.* (collectively known as "The Drug Control Act") are statutes enacted for public safety, in that they protect the public from the release of substandard and otherwise unreasonably dangerous pharmaceutical drugs and drugs into the stream of Virginia commerce.

157. As a Virginia citizen and consumer of a drug regulated by the Virginia Drug Control Act, Mrs. Bradley belongs to the class of persons for whose benefit those statutes were enacted.

158. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code § 54.1-3461(A)(2).

159. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code § 54.1-3461(B).

160. By holding and offering for sale an adulterated drug to its patients, including Mrs. Bradley, Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 54.1-3457(1), which is part of the Virginia Drug Control Act.

161. By receiving an adulterated drug in commerce and then delivering the drug for pay to its patients, including Mrs. Bradley, Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 54.1-3457(3), which is part of the Virginia Drug Control Act.

162. Mrs. Bradley contracted fungal meningitis as the result of the actions of Insight Imaging-Roanoke and its employees and agents in receiving, holding, selling, and providing to her an adulterated drug.

163. The adulterated drug injected into Mrs. Bradley's spinal canal contained fungal pathogens that proximately caused her to develop fungal meningitis.

164. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

165. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in the Commonwealth of Virginia without a valid license belongs to the category of harms against which Virginia Drug Control Act was designed to protect.

166. Therefore, each of the violations of the above statutes (Virginia Code § 54.1-3457(1), and Virginia Code § 54.1-3457(3)) by Insight Imaging-Roanoke and its employees and agents constitutes negligence *per se*, and Mrs. Bradley is entitled to the recovery of damages for her unnecessary infection and personal injury caused by that negligence *per se*.

#### **COUNT II – VIRGINIA CONSUMER PROTECTION ACT**

167. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

168. Mrs. Bradley engaged in a consumer transaction with Insight Imaging-Roanoke and its employees and agents as defined in Virginia Code § 59.1-198.

169. Insight Imaging-Roanoke and its employees and agents were suppliers of the tainted methylprednisolone acetate injected into Mrs. Bradley's spinal canal.

170. Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 59.1-200, which prohibits suppliers from misrepresenting goods as those of another, misrepresenting the source, sponsorship, approval or certification of goods, and misrepresenting that goods are of a particular standard, quality, grade or model.

171. These willful violations by Insight Imaging-Roanoke and its employees and agents resulted in Mrs. Bradley's fungal meningitis.

172. Mrs. Bradley is entitled to the recovery damages of damages for her unnecessary infection and personal injury, which occurred as the result of the violations of Virginia Code § 59.1-200 by Insight Imaging-Roanoke and its employees and agents.

173. Further, Mrs. Bradley is entitled to treble damages and an award of attorneys' fees, costs, and expenses incurred in this matter.

### **COUNT III -NEGLIGENCE**

174. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

175. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that the drugs that they purchased in order to sell and inject in their patients, including Mrs. Bradley, came from drug companies that complied with Virginia laws regarding pharmaceutical drugs ("The Virginia Drug Control Act" statutes).

176. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that their purchase of the drug they provided to Mrs. Bradley complied with the Virginia Drug Control Act.

177. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their

patients, including Mrs. Bradley, were purchased from drug manufacturers that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated.

178. Insight Imaging-Roanoke and its employees and agents had a duty to inform the doctors practicing at it, including Dr. Mathis, about the purchasing decisions by Insight Imaging-Roanoke to obtain drugs from NECC and about NECC. To the extent that they did not do so, they violated their duty and their violation prevented the doctors practicing at it, including Dr. Mathis, from making knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mrs. Bradley and their other patients.

179. Insight Imaging-Roanoke and its employees and agents had a duty to provide adequate medical oversight regarding the purchase of drugs such as the one at issue in this case. To the extent that Insight Imaging-Roanoke had no official medical director during the time and places pertinent to this action, then they delegated to non-medical staff the important patient care function of choosing safe drugs for their patients.

180. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to avoid injecting Mrs. Bradley with adulterated drugs.

181. Insight Imaging-Roanoke and its employees and agents had a duty to know what they were injecting into patients, including Mrs. Bradley.

182. Insight Imaging-Roanoke and their employees and agents had a duty to provide Mrs. Bradley reasonable care and treatment when she came to them for treatment.

183. Insight Imaging-Roanoke and its employees and agents had a duty to obtain informed consent from Mrs. Bradley for the procedure performed on her, adequately and accurately describing to her the nature of the procedure, as well as the risks of such procedure.

184. In this case, where the methylprednisolone acetate came from an unaccredited, mass producing, out-of-state, compounding pharmacy, (unregulated by the FDA and surrounded by a garbage and waste facility), Insight Imaging-Roanoke and its employees and agents had a duty to inform Mrs. Bradley of the source of the drug and the dangers associated therewith.

185. Insight Imaging-Roanoke and its employees and agents breached their duties to Mrs. Bradley in many respects:

- a. They failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Mrs. Bradley was made in compliance with Virginia pharmaceutical laws;
- b. They failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Mrs. Bradley was sold to them in compliance with Virginia pharmaceutical laws;
- c. They failed to know and understand the source and supply of the drug they provided to Mrs. Bradley;
- d. They failed to exercise reasonable and prudent care to ensure that the drug they provided to Mrs. Bradley was produced in sanitary, sterile conditions;
- e. They failed to properly inform Mrs. Bradley that the epidural steroid injection was an “off-label” application of the drug at issue, not approved by the FDA for such an application;
- f. They failed to properly inform Mrs. Bradley of the risks and dangers associated with the injection of the drug; and they failed to inform her that they had obtained the drug from NECC, the mass-producing, unaccredited, non-FDA regulated compounding pharmacy surrounded by a garbage recycling facility;
- g. Alternatively to the preceding allegation, to the extent that Insight Health unilaterally made the decision to purchase the tainted steroid and kept important information regarding the actual source and identity of the methylprednisolone acetate from Dr. Mathis, it failed to exercise reasonable and prudent care to ensure that Mrs. Bradley’s physician was adequately informed so as to allow her doctor to make knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mrs. Bradley and other similarly situated patients;
- h. They failed to exercise reasonable care to avoid injecting Mrs. Bradley with an adulterated drug;

- i. To the extent that Insight Imaging – Roanoke had no official medical director (who would have reviewed the source and supply of drugs) during the time periods relevant to this proceeding, then all or some of the defendants delegated to non-medical staff the important patient care function of choosing safe drugs for patients; and they deviated from the standard of care and breached their duties in so doing;
- j. They failed to act ethically;
- k. They failed to act with integrity;
- l. They failed to put patient care first;
- m. They failed to do the right thing;
- n. They put profits over ethics;
- o. They put profits over integrity;
- p. They put profits over patient care; and
- q. In such other manners as may be shown through discovery and at trial.

186. The negligence of Insight Imaging-Roanoke and its employees and agents proximately caused Mrs. Bradley's fungal meningitis.

187. Mrs. Bradley is entitled to the recovery of damages for her unnecessary infection and personal injury caused by the negligent acts and omissions of Insight Imaging-Roanoke and its employees and agents.

#### **COUNT IV – GROSS NEGLIGENCE**

188. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

189. The foregoing acts and omissions by Insight Imaging-Roanoke and its employees and agents went beyond mere thoughtlessness, inadvertence or error of judgment.

190. Rather, the actions of Insight Imaging-Roanoke and its employees and agents did not meet even the most minimal diligence to ensure that they were not injecting adulterated and tainted drugs directly into the bodies of their patients, including Mrs. Bradley.

191. The acts and omissions of Insight Imaging-Roanoke and its employees and agents constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Mrs. Bradley.

192. The acts and omissions of Insight Imaging-Roanoke and its employees and agents were a heedless and palpable violation of their legal duties respecting the life and rights of Mrs. Bradley. Frazier v. City of Norfolk, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

193. Mrs. Bradley's fungal meningitis occurred as a proximate result of the grossly negligent acts and omissions of Insight Imaging-Roanoke and its employees and agents.

194. Mrs. Bradley is entitled to the recovery of damages for her unnecessary infection and personal injury caused by the grossly negligent acts and omissions of Insight Imaging-Roanoke and its employees and agents.

#### COUNT V – FRAUD

195. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

196. Insight Imaging-Roanoke and its employees and agents did not inform their patients, including Mrs. Bradley, that they were providing drugs produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems described in the preceding paragraphs.

197. Insight Imaging-Roanoke and their employees and agents had a duty to inform their patients of these facts which were possessed solely by them and which they knew were unknown to Mrs. Bradley and other patients.

198. The decision by Insight Imaging-Roanoke and its employees and agents not do so constituted actual and/or constructive fraud.

199. Insight Imaging-Roanoke and its employees and agents had a duty to adequately inform the doctors practicing at it, including Dr. Mathis, about the purchasing decisions by Insight Imaging-Roanoke to obtain drugs from NECC and about NECC. To the extent that they did not do so, they violated their duty and their violation prevented the doctors practicing at it, including Dr. Mathis, from making knowledgeable and professionally decisions to reject such drugs on behalf of Mrs. Bradley and their other patients.

200. Insight Imaging-Roanoke and its employees and agents provided patients, such as Mrs. Bradley, with written false documentation asserting that the drug injected was, in fact, the name brand drug produced by the FDA-regulated manufacturer, Pfizer.

201. Also, Insight Imaging-Roanoke and its employees and agents provided patients, such as Mrs. Bradley, with written false drug code documentation asserting that the drug injected into the patient was, in fact, the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

202. Within the context of the healthcare provider-patient relationship, Mrs. Bradley relied upon the superior knowledge of Insight Imaging-Roanoke and its employees and agents concerning the drug, source of the drug, and cost of the drug in accepting their representation that the methylprednisolone acetate was safe and effective.

203. Insight Imaging-Roanoke and its employees and agents provided Mrs. Bradley with a knock-off drug obtained from an unaccredited compounding pharmacy, unregistered to distribute wholesale in Virginia, and not preferred by insurance companies – including Mrs. Bradley’s insurance company, without disclosing information about its source.

204. In so doing, Insight Imaging-Roanoke and its employees and agents concealed facts material to Mrs. Bradley’s treatment, knowing Mrs. Bradley acted on the belief that no such facts existed, and that Mrs. Bradley relied upon it to obtain and inject safe drugs.

205. By representing that the drug injected was obtained from an FDA-regulated manufacturer, Insight Imaging-Roanoke and its employees and agents misrepresented a material fact regarding Mrs. Bradley’s treatment.

206. Rather than properly informing its patients, including Mrs. Bradley, of these crucial facts, Insight Imaging-Roanoke and its employees and agents falsely represented the drug at issue as “Depo-Medrol,” the trademarked name brand used by Pfizer; and falsely coded it as the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

207. This pattern of deception by Insight Imaging-Roanoke and its employees and agents was repeated to Mrs. Bradley’s primary care physician.

208. This pattern of deception by Insight Imaging-Roanoke and its employees and agents was also repeated for billing purposes to Mrs. Bradley’s insurance company, where Insight Imaging-Roanoke falsely used the National Drug Code, 0703-0051-01, a unique product code assigned to the completely unrelated FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc.

209. Insight Imaging-Roanoke also used an HCPCS “J” code inappropriate and misleading for compounded drugs.

210. Such actions by Insight Imaging-Roanoke and its employees and agents show affirmative misrepresentations of the identity of the drug provided to Mrs. Bradley and a knowing, deliberate decision not to disclose the source of the “drug” provided to Mrs. Bradley.

211. As a third party payor and agent authorized to receive medical invoices for processing on behalf of Mrs. Bradley, misrepresentations to her health insurer constitute misrepresentations to Mrs. Bradley.

212. Mrs. Bradley’s health insurer, like many such third-party payors, maintains policies discouraging the use of compounded drugs.

213. For example, Anthem Blue Cross states as follows:

Compounded medications are customized medication(s) ... that are not commercially available ... However, they are not approved by the U.S. Food and Drug Administration (FDA) nor are they approved by our Pharmacy and Therapeutics process. **Since there is limited oversight in the preparation of these compounded medications, there is a possibility that patients may be put at risk when prescribed a compounded medication that is not subject to quality testing that validates purity, stability or dosage...** Thus, due to the lack of data to adequately review these medications, compounded medications are considered **non-preferred...** They may also require prior authorization of benefits for coverage through a participating network pharmacy...

214. On information and belief, Insight Imaging-Roanoke and its employees and agents knew that using drugs from compounding pharmacies would present billing issues and problems with reimbursement.

215. On information and belief, Insight Imaging-Roanoke and its employees and agents knew that properly coding the drugs injected into Mrs. Bradley and other patients would cause concerns and “red flags” with insurance companies, such as the one serving Mrs. Bradley.

216. Accordingly, on information and belief, Insight Imaging-Roanoke and its employees and agents specifically chose to falsely describe the drugs provided as part of a scheme and common practice or design, intended to prevent insurance companies from realizing the nature and source of the drugs being injected into patients, such as Mrs. Bradley.

217. Insurance companies, such as the one serving Mrs. Bradley, act as a protective information source and gatekeeper for their customers.

218. Here, Insight Imaging-Roanoke and its employees and agents engaged in the same pattern of behavior (and the same specific misrepresentations to patients, referring primary care physicians, and insurers provided by the defendants to Mrs. Bradley, her doctor and her insurer) with many other patients receiving epidural steroid injections.

219. These specific actions relating to Mrs. Bradley and the prolonged pattern of deception prevented Mrs. Bradley's insurer from properly performing its protective role. As a result, Insight Imaging-Roanoke was able to continue its practice of purchasing methylprednisolone acetate from NECC and passing it off as a manufactured and safe drug.

220. Under these circumstances, misrepresentations to Mrs. Bradley's insurer – particularly as part of a pattern of conduct – constituted misrepresentations to Mrs. Bradley that were material and relied upon to her detriment.

221. Insight Imaging-Roanoke and its employees and agents misrepresented that the knock-off drug obtained from NECC and injected into Mrs. Bradley's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory; they misrepresented the code for such drug as the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc.

222. These representations (and the pattern of which they were a part) were false and deceptive, were relied upon to the detriment of Mrs. Bradley (and/or her agent insurer) and other patients, and caused harm to Mrs. Bradley.

223. Insight Imaging-Roanoke and its employees and agents knew, or should have known, these representations to be false.

224. These representations and the pattern of similar behavior by Insight Imaging-Roanoke and its employees and agents constitute actual or constructive fraud.

**CERTIFICATION PURSUANT TO VIRGINIA CODE § 8.01-20.1**

225. Mrs. Bradley certifies that she complied with Virginia Code § 8.01-20.1 before requesting service of process upon the defendants.

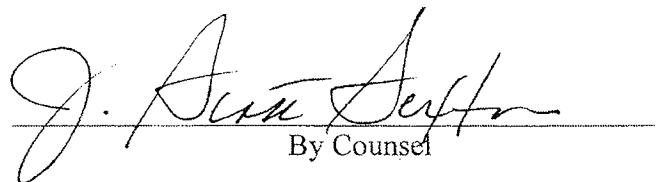
**REQUEST FOR TRIAL BY JURY**

226. Mrs. Bradley requests trial by jury on all issues.

**PRAYER FOR RELIEF**

WHEREFORE, Dana M. Bradley, by counsel, moves this Court for judgment against the defendants, jointly and severally, in the amount of five million dollars (\$5,000,000) plus her taxable costs with pre-verdict interest from August 29, 2012 and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages, trebled damages, attorney's fees, and costs.

DANA MARLENE BRADLEY,



J. Scott Sexton  
By Counsel

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*Counsel for Dana Marlene Bradley*



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EXHIBIT A

## MAKE CHECKS PAYABLE TO:

Insight Imaging Roanoke  
PO Box 843086

Los Angeles, CA 900843086

STATEMENT DATE	PAY THIS AMOUNT	ACCOUNT NBR
11/09/12	CONTINUED	
SHOW AMOUNT PAID HERE		

## STATEMENT

## ADDRESSEE:

BRADLEY, DANA

## REMIT TO:

Insight Imaging Roanoke  
PO Box 843086  
Los Angeles, CA 900843086

Please check box if above address is incorrect or insurance information has changed, and indicate change(s) on reverse side.

PLEASE DETACH AND RETURN TOP PORTION WITH YOUR PAYMENT

DATE	DESCRIPTION OF SERVICE	AMOUNT	INSUR BALANCE	PATIENT BALANCE	BALANCE
08/02/12	ENCOUNTER FOR DANA WITH OBIEN MD, ROBERT				
08/02/12	72148-G - MRI, LUMBAR SPINE WITHOUT CONTRAST				
08/17/12	Medicare Write OFF (CREDIT)				
08/17/12	PAYMENT				
09/10/12	PAYMENT				
08/02/12	72146-G - MRI, THORACIC SPINE WITHOUT CONTRAST				
08/17/12	Medicare Write OFF (CREDIT)				
08/17/12	PAYMENT				
09/10/12	PAYMENT				
	ENCOUNTER TOTAL	\$0.00	\$0.00	\$0.00	
08/29/12	ENCOUNTER FOR DANA WITH MATHIS MD, JOHN				
08/29/12	62311-G - INJ 1 NOT LYTIC-WWO CM-DX/ITX-EPIDUR; LUMB/SAC				
09/14/12	Medicare Write OFF (CREDIT)				
09/14/12	PAYMENT				
10/02/12	PAYMENT				
08/29/12	77003-G - FLUOROSCOPIC GUIDANCE AND LOCALIZATION OF NE...				
09/14/12	Medicare Write OFF (CREDIT)				
09/14/12	PAYMENT				
10/02/12	PAYMENT				
08/29/12	00270141125C - ISOVUE M 200 BRACCO (QTY 2)				
09/14/12	Medicare Write OFF (CREDIT)				
09/14/12	PAYMENT				
10/02/12	PAYMENT				
08/29/12	00703005101M - DEPO-MEDROL, METHYLPREDNISOLONE				
09/14/12	Medicare Write OFF (CREDIT)				
09/14/12	PAYMENT				
10/02/12	PAYMENT				
08/29/12	00409488820M - SODIUM CHLORIDE INJECTION				
09/14/12	Medicare Write OFF (CREDIT)				
ACCOUNT NBR	CURRENT	30 DAYS	60 DAYS	90 DAYS	120 DAYS
	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
					\$0.00

MESSAGE:

PLEASE PAY  
THIS AMOUNT »»» CONTINUED

\*\* PAYMENT DUE UPON RECEIPT \* THANK YOU \*\*  
STATEMENT,

EXHIBIT B

**MAKE CHECKS PAYABLE TO:**

Insight Imaging Roanoke  
PO Box 843086

Los Angeles, CA 900843086

STATEMENT DATE	PAY THIS AMOUNT	ACCOUNT NBR
11/09/12	\$0.00	\$
	SHOW AMOUNT PAID HERE	\$

## STATEMENT

**ADRESSEE:**

REMIT TO:

BRADLEY, DANA

Insight Imaging Roanoke  
PO Box 843086  
Los Angeles, CA 900843086

Please check box if above address is incorrect or insurance information has changed, and indicate change(s) on reverse side.

PLEASE DETACH AND RETURN TOP PORTION WITH YOUR PAYMENT

**MESSAGE:**

PLEASE PAY  
THIS AMOUNT >>>> \$0.00

\*\* PAYMENT DUE UPON RECEIPT \* THANK YOU \*\*  
STATEMENT

John M. Mathis, M.D.,M.Sc

**INSIGHT**  
IMAGING

INSIGHT IMAGING - ROANOKE  
2922 FRANKLIN ROAD S.W.  
ROANOKE, VA 24014

Tel. 540.581.0882  
Fax: 540.581.0881

[www.insighthealth.com](http://www.insighthealth.com)

Date: \_\_\_\_\_

Injection dosage: Depo-Medrol 80mg / 40mg

Steroids typically take 12 to 24 hours before they start to work.  
Maximum effect can take up to 7 – 10 days.

Call **Insight Imaging (540-581-0882)** in a week if symptoms have not subsided to schedule another injection. If you already have an appointment scheduled with Insight, keep that appointment unless otherwise directed by your physician.

If your pain has completely resolved, and you no longer need your follow up appointment, please call **Insight Imaging** to cancel your future injection.

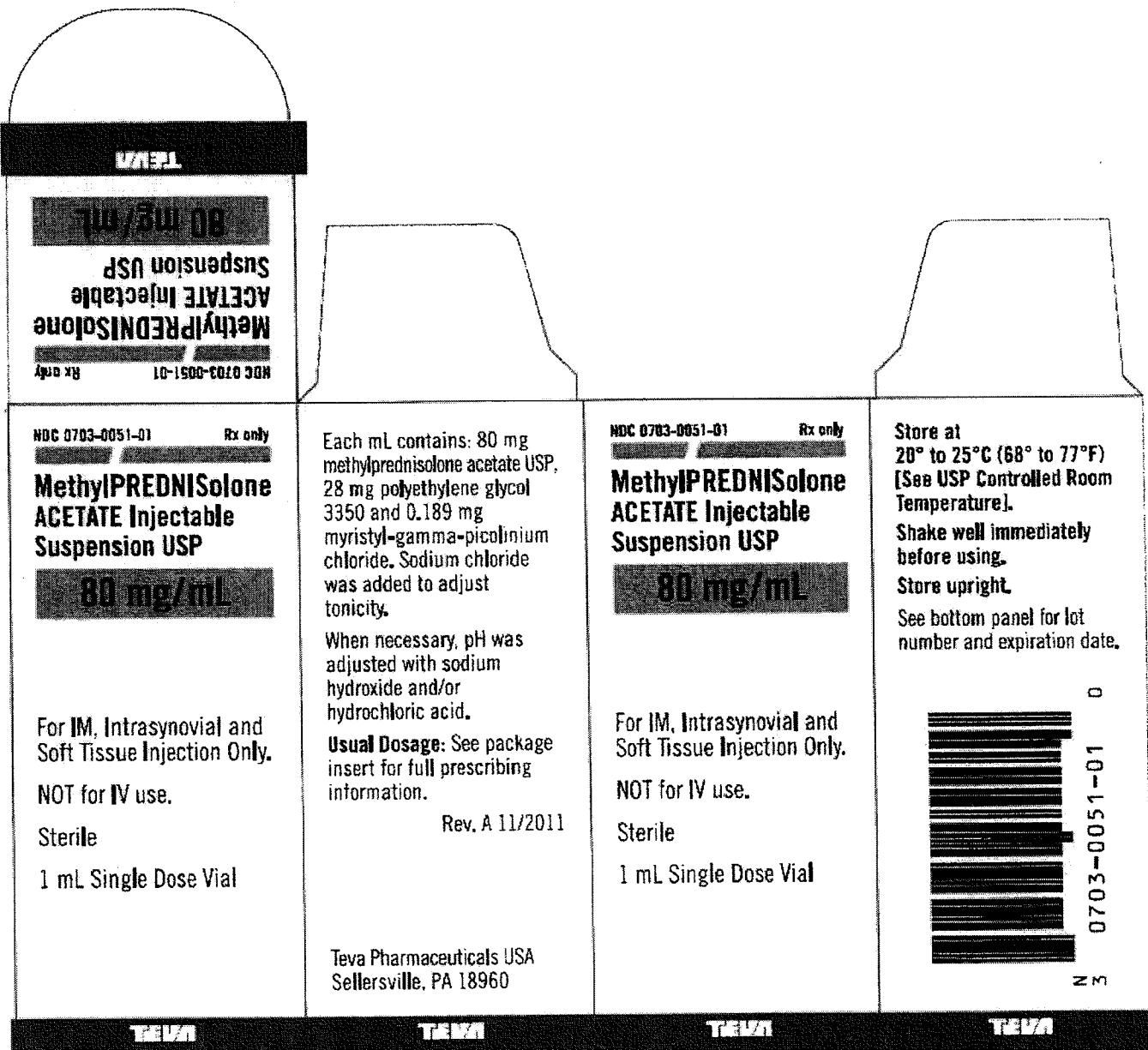
Continue to take pain meds if needed.  
Heat or ice may be used as well.

Symptoms can worsen before seeing improvement.

\*\*\*\*Call your Doctor that monitors your Diabetes or Blood Pressure if you feel you are higher than the guidelines set by your physician.

**EXHIBIT C**

## PRINCIPAL DISPLAY PANEL





**Insight Imaging – Roanoke**  
2923 Franklin Road  
Roanoke, VA 22206  
PH# 540.581.0882  
FAX# 540.581.0881

**PATIENT NAME:** BRADLEY, DANA

**PATIENT DOB:**

**DATE OF EXAM:** 08/29/2012

**REQUESTED BY:** TREVOR CHAPMON, MD

**EXAM:** INJ 1 NOT LYTIC-W/WO CM-DX/TX-EPIDUR; LUMB/SAC

**CLINICAL HISTORY:** Back and leg pain.

**INJECTION SITE:** L4-5 translaminar.

The patient was placed prone on the radiographic table and the lumbar region prepared and draped in a sterile manner. Local anesthesia was applied and subsequently, a 25-gauge needle was directed into the epidural space using fluoroscopic guidance. The needle position was confirmed fluoroscopically and with contrast injection showing flow into the epidural space. There is no flow into the subarachnoid space or into a vessel.

Depo-Medrol 80 mg, 1 mL of 0.25% bupivacaine and 7 mL of normal saline was subsequently injected and tolerated well by the patient with no complication.

**IMPRESSION:**

NORMAL LUMBAR EPIDURAL STEROID INJECTION.

Thank you for this referral.

John M. Mathis, M.D.

JMM/mm

D: 08/29/2012 06:34:30PDT

T: 08/29/2012 06:35:29PDT

Doc ID: 12041414/Insight Job ID: 2267316/NTS Job ID: 2267316/10210995  
10210995

Document authenticated by John M. Mathis, M.D., on 08/29/2012 07:24:13PDT

**Procedure Completion**

Patient Name: BRADLEY, DANA DOB: 8/29/2012 Visit: Service Date: 8/29/2012 Is Patient Pregnant: Yes Date of LMP: 6/25/2012 Appt Type: S No MM/DD/YY

Accession CPT Code: CPT Description: Modality: Start Time: End Time:  
10210995 62311 EPIDURAL(ESI) LUMBAR SPC 9:15 AM 9:45 AM

Performed Procedure: 10210995

Prm Diag	PD	CPT Cd/Desc	62311	EPIDURAL(ESI) LUMBAR	Copy	
		Start/End	9:20 AM	9:35 AM	Qty	1
		Contrast Seq w/	Seq w/o	Total	0.00	
		Radiologist	MATHIS	JOHN		
		Radiation Dose	No Dose Available	DLP mGy-cm	Misc. Info	
		Cancellation				

Additional Charges

HCPCS\_A4649 - SURGICAL SUPPLY: MISCELLANEOUS  
 77003 - FLUOROSCOPIC GUIDANCE AND LOCALIZATION

Contrast/Isotope/Sedation/Supplies

Bill Qty	HCPCS Cd	HCPCS Description	NDC	Accession
2	Q9966	LOW OSMOLAR CONTRAST MATERIAL, 200-299 MG/ML IODINE	00270141125	10210995
1	J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG	00703005101	10210995
1	A4216	STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH,	00409488820	10210995
1	J3490	UNCLASSIFIED DRUGS	00409155910	10210995

Sedation/Meds

Contrast	Edit	Brand	DEPCHEEDE METHYL PREDNISOLONE
Sed/Med	Delete	Strength	80 MG/ML
Isotope		Route	EPIDURAL
Supply		NDC #	00703005101
		Amt Admin	ML
		Sedation Note	
		Lot #	0629120124
		Exp. Dt	12/26/2012
		Admin By	JMM [Initials]
			OK
			Cancel